FDA 510(k) Premarket Notification

# K161355 invendoscopy E200 System

**CLEARED**

Aug 25, 2016
101 days to decision

K161355 · Product code: **FDF** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k161355/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Colonoscope And Accessories, Flexible/rigid (FDF) |
| Date received | May 16, 2016 |
| Decision date | Aug 25, 2016 |
| Days to decision | 101 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Invendo Medical GmbH** |
| Location | Kissing, DE |
| Contact | Oliver V. Ruepprecht |
| 510(k) history | 2 submissions · 2 cleared · 2016-2018 |

**510k Database** - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k161355/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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